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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,339	03/31/2004	Vilmos Keri	2664/58004	7521
26646	7590	03/23/2006	EXAMINER	
KENYON & KENYON LLP ONE BROADWAY NEW YORK, NY 10004			KUNEMUND, ROBERT M	
			ART UNIT	PAPER NUMBER
			1722	
DATE MAILED: 03/23/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/815,339	<b>Applicant(s)</b> KERI ET AL.	
	<b>Examiner</b> Robert M. Kunemund	<b>Art Unit</b> 1722	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-36 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 to 5, 7 to 13, 15 to 19, 21 to 27, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gletos (5,508,398).

The Gletos reference teaches a method of crystallizing macrolides, note entire reference. A macrolide starting material is combined with two solvents, one polar and one a hydrocarbon, note, col.3. The hydrocarbon solvent can be toluene and the polar solvent can be ethyl acetate, note col. 4. The pH of the solution is adjusted either with an aqueous acid or base, note examples. This adds the water to the solution. The temperatures of crystallization are 40°C or lower. The macrolide is then crystallized

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isolated and recovered. The sole difference between the instant claims and the prior art is the two phases. However, it would have been obvious to one of ordinary skill in the art to have the two phases as one solvent is water immiscible which would inherently and obviously create two phases of the solutions and crystallize from the phase which as the marcolibe.

Claims 6, 20, 29 to 32 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gletos (5,508,398).

The Gletos reference is relied on for the same reasons as stated, supra, and differs from the instant claims in the time and temperatures of mixing. However, in the absence of unexpected results, it would have been obvious to one of ordinary skill in the art to determine through routine experimentations the optimum, operable temperature and times in the Gletos reference in order to ensure full mixing of the contents and increased crystallization rates.

Claims 14, 28 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gletos (5,508,398) in view of Navarro (wo 00/33878).

The Gletos reference is relied on for the same reasons as stated, supra, and differs from the instant claims in the specific marcolides. However, the Navarro reference teaches crystallizing macrolides like ascomycins, note page 3. It would have been obvious to one of ordinary skill in the art to modify the Gletos process by the teachings of the Navarro reference to crystallize a specific marcolide in order to crystal them for use in pharmaceuticals.

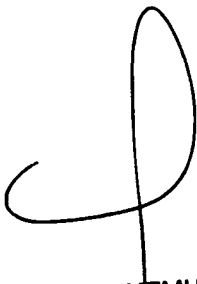
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kunemund whose telephone number is 571-272-1464. The examiner can normally be reached on 8 hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Duane Smith can be reached on 571-272-1166. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RMK



ROBERT KUNEMUND  
PRIMARY EXAMINER